



DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD

Federal Preemption of State Tort Suits under the Medical Device Amendments of 1976

The Harvard community has made this article openly available.
[Please share](#) how this access benefits you. Your story matters.

Citation	Alissa Danielle Jijón, Federal Preemption of State Tort Suits under the Medical Device Amendments of 1976 (2008)
Accessed	February 19, 2015 9:16:33 AM EST
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:7702808
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

(Article begins on next page)

**Federal Preemption of State Tort Suits under the
Medical Device Amendments of 1976**

Alissa Danielle Jijón
Class of 2008
May 2008

This paper is submitted in satisfaction of the course requirement and
the third year written work requirement.

Abstract

Historically, plaintiffs injured by allegedly defective medical devices were able to bring tort suits against manufacturers in state court. With the passage of the Medical Device Amendments of 1976 (“MDA”) – a federal law containing an express preemption clause – many wondered whether such lawsuits would still be viable. Courts, FDA, device manufacturers, and the public alike have struggled to understand the scope of federal preemption under the new regime. This paper documents that struggle, beginning with the passage of the MDA in 1976. It then focuses on the Supreme Court’s landmark ruling on the issue twenty years later in *Medtronic v. Lohr*. It discusses the evolution of MDA preemption doctrine in the post-*Lohr* decade, and then addresses the Court’s most recent word on the subject – *Medtronic v. Riegel*. The paper concludes with a description of the most current understanding of federal preemption under the MDA and implications for the future of the field.

Table of Contents

Introduction.....	1
Part I: A Brief History of Medical Device Regulation.....	3
(A) <i>Device Classification under the MDA</i>	<i>5</i>
(B) <i>Pre-market Review of Class III Devices</i>	<i>6</i>
(C) <i>Preemption under the MDA.....</i>	<i>8</i>
(i) <i>Scope of Preemption: Congressional Intent</i>	<i>11</i>
(ii) <i>Scope of Preemption: FDA Interpretation.....</i>	<i>13</i>
(iii) <i>Scope of Preemption: The Courts Speak</i>	<i>14</i>
Part II: <i>Medtronic v. Lohr</i>	17
(A) <i>Does the preemption clause of the MDA apply to state common-law tort actions?.....</i>	<i>18</i>
(B) <i>Does preemption under the MDA apply to this case involving a Class III medical device that underwent FDA's section 510(k) review?</i>	<i>21</i>
(i) <i>Specificity of federal regulations</i>	<i>21</i>
(ii) <i>Specificity of state regulations</i>	<i>23</i>
(iii) <i>Parallel duties in state and federal law not preempted</i>	<i>25</i>
Part III: Preemption under the MDA in the Years between <i>Lohr</i> and <i>Riegel</i>	27
(A) <i>The FDA Responds to Lohr</i>	<i>28</i>
(B) <i>Trends in Preemption in the Post-Lohr period.....</i>	<i>29</i>
(C) <i>FDA Changes its Mind</i>	<i>33</i>
(D) <i>The Courts Respond Inconsistently</i>	<i>34</i>
Part IV: <i>Medtronic v. Riegel</i>	36
(A) <i>Did the federal government establish requirements applicable to the Evergreen Balloon within the meaning of § 360k(a) of the MDA?</i>	<i>38</i>

(B) Did the Riegels’ common-law claims rely upon any “requirements” under New York law that are specific enough to invoke § 360k(a) preemption?39

Part V: Post-Riegel Wranglings.....43

Conclusion52

Introduction

Imagine two characters awake late at night on February 19, 2008. One, Jane Doe, is the in-house counsel for Acme, a major medical device manufacturer. The company has been manufacturing artificial joints for years, and the products have improved the lives of countless patients. Unfortunately, some patients have had trouble with the joints, and are suing the company for allegedly defective design. The other person is John Doe, a hospital patient awaiting surgery to remove a faulty artificial hip joint manufactured by Acme. He is exhausted, in pain, and outraged that he has to undergo another invasive procedure. His physicians have told him that his synthetic joint was defective to start with, and he wants to hold someone accountable for his suffering.

What Jane suspects, and what John likely does not, is that the next day will change both their futures. The pending lawsuits against Jane's company are about to disappear, and John's ability to sue is about to be radically undercut. On February 20, 2008, the Supreme Court rendered its decision in the medical device-related case, *Medtronic v. Riegel*, and the litigation landscape may never look the same again.

Before launching into how *Medtronic v. Riegel* changed product liability in the field of medical devices, let us return to John's predicament to see why this case would affect him at all. John's artificial joint is a medical device regulated by the Food and Drug Administration ("FDA"). John had the joint implanted months ago after his own hip joint had deteriorated from age. Unfortunately, the synthetic plastics in the joint degraded rapidly and the mechanism became irreparably deformed. John was left in a great deal of pain, and the only real solution was to surgically remove and replace the faulty joint. John is understandably upset, and he decides to sue Acme for his injury in a Massachusetts court. This is where things get complicated.

Whether a medical device defect claim can be successfully litigated in state court depends on a host of factors, including: the nature of the claim, the type of device, the means by which the device was examined by FDA before being commercially marketed, and the controlling judicial understanding of federal preemption at the time. The final factor is probably the most crucial in determining the fate of John's suit, and it is the most comprehensive, as it relies on an analysis of all the others.

Our understanding of the scope of federal preemption of state tort suits in the domain of medical devices has changed over time. In the early days of FDA regulation, not much attention was paid to devices, as compared to food or drugs. States were fairly free to deal with the production and sale of medical devices as they saw fit. With time and technological advances, medical devices grew more complex and potentially more dangerous. In response to growing concerns about consumer safety, FDA and Congress began to regulate more rigorously, setting up a regime in which federal regulation occupied the front line in the war against dangerous devices. Because this represented a shift in the regulatory balance from states to the federal government, it took some time to shape the contours of each system's powers. In the latter half of the twentieth century, it seemed clear that *some* forms of state regulation would be pre-empted by federal law, but the precise reach of preemption would take decades to determine.

Perhaps the two most important preemption decisions in the medical device litigation realm are the Supreme Court juggernauts, *Medtronic v. Lohr* and *Medtronic v. Riegel*. Both cases came on the heels of years of inconsistent decisions in the district and Circuit courts. Each case served to clarify pre-existing misconceptions, while at the same time raising brand new questions. This paper will provide a brief history of our understanding of federal preemption in the field of medical device litigation, and it will pay particular attention to the two landmark *Medtronic* rulings. Part I of the paper will provide an overview of the

regulation of medical devices in United States history, ending with the enactment of the statute that remains at the heart of the preemption debate: The Medical Device Amendments of 1976 (“MDA”). Part II will discuss *Medtronic v. Lohr*, the first Supreme Court case to tackle the subject of federal preemption under the MDA. Part III will delve into what the preemption landscape looked like in the post-*Lohr* era. It will explore the gaps left by the *Lohr* decision and how courts and FDA attempted, and failed, to fill them. Part IV will discuss the Court’s latest word on preemption: *Medtronic v. Riegel*. Part V will discuss the potential impact of the *Riegel* decision and what the most current understanding of federal preemption under the MDA seems to be. The paper will conclude with implications for the future of product liability litigation in the field of medical devices.

Part I: A Brief History of Medical Device Regulation

The regulation of medical devices in the United States does not have much history to speak of until 1938.¹ Although Congress passed laws addressing the problem of adulterated or misbranded foods and drugs as early as 1906,² it took the federal government three more decades to address medical devices. In the late 1930s, Congress broadened its 1906 Act to encompass devices, and the resulting legislation was the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”).³ The FDCA granted FDA power to prohibit adulteration or misbranding of medical devices that traveled in interstate commerce. After the passage of the

¹ BRADLEY MERRILL THOMPSON, FDA REGULATION OF MEDICAL DEVICES 3 (1995).

² Federal Food and Drugs Act of 1906, 59 Pub. L. No. 384; 34 Stat. 768 (1906). 1906 also ushered in the “modern era” of FDA because the Act added regulatory functions to the agency’s previous purpose of scientific inquiry. John P. Swann, History of the FDA (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT (George Kurian, ed., Oxford University Press, 1998)), <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Apr. 28, 2008).

³ 75 Pub. L. No. 717; 52 Stat. 1040 (1938).

Act, however, “quack” devices still proliferated.⁴ As the decades passed, more complex devices were invented, including pacemakers, heart valves, dialysis machines, and a host of other products that posed new dangers to consumers.⁵ Under the FDCA, FDA was generally able to remove dangerous devices from the market, but it did not have the ability to engage in pre-market review. In order to best protect consumers from these new and untested technologies, FDA asked Congress to expand its authority.⁶

In the 1970s, under the Nixon Administration, the Secretary of Health, Education, and Welfare convened a study group to investigate the need for more stringent medical device controls. The group was called the Cooper Committee,⁷ and it discovered that medical devices had led to numerous injuries and deaths.⁸ The Committee’s suggestions about creating a classification system, promulgating standards for the production of devices, and engaging in pre-market safety review heavily influenced legislative action.⁹ Congress was also acutely aware of many high-profile medical device failures, such as that of the Dalkon Shield.¹⁰ It responded to the growing crisis with the enactment of the Medical Device Amendments of 1976 (“MDA”),¹¹ and this ushered in the modern era of device regulation.¹²

⁴ THOMPSON, *supra* note 1, at 4 (citing Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 102, 105 (1989)).

⁵ PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW* 969 (3d ed. 2007) (citing H. COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94th Cong. (1st Sess. 1975)).

⁶ THOMPSON, *supra* note 1, at 5.

⁷ The group was headed by Dr. Theodore Cooper, Director of the National Heart and Lung Institute, and most of its members were government representatives. *Id.* at 6.

⁸ Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2129 (2000) (internal citations omitted).

⁹ See HUTT, MERRILL & GROSSMAN, *supra* note 5, at 979 (citing STUDY GROUP ON MED. DEVICES, DEP’T. OF HEALTH, EDUC., & WELFARE, *MEDICAL DEVICES: A LEGISLATIVE PLAN* (1970)).

¹⁰ The Dalkon Shield was a widely-used intrauterine device (“IUD”) that had been placed on the market in 1970 and that was later linked to infections, miscarriages and deaths. *See, e.g.* H.R. REP. NO. 94-853, at 8 (1976) (“Significant defects in cardiac pacemakers have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972.”); S. REP. NO. 94-33, at 6 (1975) (“Some 10,000 injuries were recorded, of which 731 resulted in

The MDA expanded the scope of FDA's authority in significant ways. The most important changes for the purpose of this paper are those pertaining to device classification, pre-market review, and federal preemption.

(A) Device Classification under the MDA

Under the MDA, medical devices are categorized into three classes, each defined by the "type of regulation that is necessary to ensure the safety and effectiveness of products in that category."¹³ Class I devices are items such as tongue depressors, bandages, and bedpans.¹⁴ They pose the least risk to consumers, and thus, the "general controls" of the MDA are sufficient to assure their safety and effectiveness.¹⁵ Class II devices are products such as syringes, hearing aids, and resuscitation equipment. This category contains devices that are potentially more harmful to consumers, and FDA requires more than just compliance with general controls to ensure safety and effectiveness.¹⁶ Manufacturers of these devices must comply with federal performance standards known as "special controls."¹⁷ Finally, Class III devices are those that pose the highest risk;¹⁸ they are products such as pacemakers, IUDs, artificial hearts, and artificial joints. These are subject to the strictest type of regulatory requirement; they must undergo a pre-market review process in which FDA

death. For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices."); 122 Cong. Rec. 5859 (1976) (remarks of Rep. Waxman) ("A 10-year FDA death-certificate search found over 850 deaths tied directly to medical devices.").

¹¹ 94 Pub. L. No. 295; 90 Stat. 539 (1976).

¹² See Green & Schultz, *supra* note 8, at 2129-31.

¹³ THOMPSON, *supra* note 1, at 41.

¹⁴ *Id.*

¹⁵ 21 U.S.C. § 360c(a)(1)(A) (2000). Note that statutory references in this paper are generally to the United States Code. In certain cases, where relevant, a parallel citation to the FDCA will be given as well.

¹⁶ THOMPSON, *supra* note 1, at 42.

¹⁷ 21 U.S.C. § 360c(a)(1)(B) (2000).

¹⁸ Class III devices are those that either "present a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C) (2000).

inspects valid scientific evidence of their safety and effectiveness.¹⁹ Class III devices are the focus of this paper because they are the most stringently regulated by FDA, and this places them at the heart of product liability lawsuits and the federal preemption debate.

(B) Pre-market Review of Class III Devices

In order to sell a Class III medical device on the market, a manufacturer must provide FDA with a “reasonable assurance” that its product is safe and effective.²⁰ Strictly speaking, this entails a fairly intensive procedure referred to as “premarket approval” (“PMA”).²¹ PMA is a “rigorous process” in which manufacturers supply FDA with detailed safety and efficacy data.²² However, when the MDA went into effect, Congress knew that it would be both impracticable and undesirable to subject *all* pre-amendment Class III devices to PMA review. Certainly it would have dealt a devastating blow to many perfectly safe and well-established devices, as they would all have to have been pulled from the market until FDA completed its lengthy reviews. At the same time, it would have been unfair if the PMA process was only required for post-amendment devices. Older products would have been able to remain on the market and would-be entrants would have been hampered in their ability to compete, even if their products were essentially the same as some of the pre-amendment devices.²³ In order to facilitate a smooth transition between the pre- and post-MDA regulatory regimes,²⁴ FDA permitted Class III devices some alternate modes of entry into (or permission to remain on) the market.²⁵

¹⁹ THOMPSON, *supra* note 1, at 42.

²⁰ See 21 U.S.C. § 360e(d)(2) (2000).

²¹ The information that a manufacturer must submit to FDA in a PMA application in order to gain approval is detailed in 21 U.S.C. § 360e(c) (2000); FDCA § 515(c).

²² Scott W. Sayler & Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After Medtronic, Inc. v. Lohr*, 6 ANNALS HEALTH L. 185, 186 (1997).

²³ HUTT, MERRILL & GROSSMAN, *supra* note 5, at 987-88.

²⁴ There have been medical device-related amendments since 1976, such as the Safe Medical Devices Act of 1990 (“SMDA”). While these subsequent laws have made changes to the

Sections 513(f)(1)(A)²⁶ and 515(b)(1)²⁷ of the MDA granted pre-amendment Class III devices and post-amendment Class III devices *that were substantially equivalent to pre-amendment Class III devices* an exemption from the PMA process.²⁸ Pre-amendment devices could thus remain on the market, and substantially equivalent new devices could gain access to the market easily through an abbreviated review. If a Class III device produced today is “substantially equivalent” to a pre-existing device, the product can be marketed without undergoing PMA provided that the manufacturer submits a “premarket notification” (“PMN”) to FDA.²⁹ This is commonly referred to as the “section 510(k) process,”³⁰ and it is the simplest route for a Class III device to get onto the market.³¹ FDA also permits “piggy-

regulatory scheme, a detailed exploration of their impact is beyond the scope of this paper. Thus, when I make reference to the post-1976 regulatory scheme, I do not mean to suggest that all modern regulations were codified in the original MDA, and I will provide citations to updated statutory provisions where relevant.

²⁵ One mode of Class III device exemption that will not be discussed in detail in this paper is the Investigational Device Exemption (“IDE”). Because Congress wanted to encourage “the discovery and development of useful devices,” this exemption allows some Class III products that are still under development to reach the market. 21 U.S.C. § 360j(g)(1) (2000); FDCA § 520(g)(1). FDA grants permission for use of these devices in clinical investigations. *See* 21 U.S.C. § 360j(g)(2)(A) (2000); FDCA § 520(g)(2)(A).

²⁶ 21 U.S.C. § 360c(f)(1)(A) (2000).

²⁷ 21 U.S.C. § 360e(b)(1) (2000).

²⁸ Even though FDA “grandfathered” in pre-1976 devices and allowed post-1976 devices a shortcut onto the market, the agency still reserved the right to promulgate regulations triggering approval requirements for a specific category of device. If FDA determined that it wanted to review safety and efficacy of a particular category of Class III device, it would promulgate regulations notifying the manufacturers that they needed to submit PMA applications. This call for PMAs would also apply to any post-amendment products that had entered the market by virtue of being “substantially similar” to the pre-amendment category under review. HUTT, MERRILL & GROSSMAN, *supra* note 5, at 988.

²⁹ 21 U.S.C. § 360(k) (2000); FDCA § 510(k).

³⁰ It is so called after the pertinent section in the original Act, FDCA § 510(k); 21 U.S.C. § 360(k) (2000). Medical devices that are approved for sale in this manner are sometimes called “510(k) devices.” Sayler & Thomas, *supra* note 22, at 187.

³¹ Section 510(k) submissions require less information from the manufacturer, are statistically more likely to be approved by FDA, and by law, must be completed more quickly than PMAs. FDA has 90 days by statute to respond to a section 510(k) notification and 180 days to respond to a PMA. Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L. J. 510, 515-18 (1984).

backing,” or the approval of a new device based on its substantial equivalence to another post-amendment device that was itself approved pursuant to the section 510(k) process.³²

The PMA application has been described as a “voluminous and detailed submission”³³ and it involves review of copious information regarding device safety and efficacy. Conversely, the section 510(k) process is much shorter and does not always include clinical data.³⁴ While FDA takes an average of 1,200 hours to complete a PMA review, it completes a section 510(k) review in only about 20 hours.³⁵ Most Class III devices have been subjected to section 510(k) review only, and this still remains the dominant mode of market entry.³⁶

The distinctions between PMA and section 510(k) review are critical to the federal preemption debate because the former process bespeaks significant federal regulation while the latter is comparatively cursory. Since the principal debate in federal preemption is whether state laws and regulations should be subjugated to federal ones, a detailed consideration of the method of pre-market review is necessary to determine whether the federal government may be said to be “regulating” a product at all.

(C) Preemption under the MDA

In order to fill the void that existed in the absence of federal regulation before the MDA was enacted, some states passed legislation to protect their consumers from medical devices. For example, California – in response to the Dalkon Shield tragedy – had passed laws requiring state pre-market approval for IUDs, and New Jersey had laws regulating

³² Green & Schultz, *supra* note 8, at 2135.

³³ Michael K. Carrier, *Federal Preemption of Common Law Tort Awards by the Federal Food, Drug, and Cosmetic Act*, 51 FOOD & DRUG L.J. 509, 550 (1996) (citing Edward M. Basile, *Using the Product Approval Process to Protect Market Share: What are the Risks and Benefits*, 44 FOOD DRUG COSM. L.J. 165, 166 (1989)).

³⁴ *Id.* at 550 (citing Edward M. Basile, *Using the Product Approval Process to Protect Market Share: What are the Risks and Benefits*, 44 FOOD DRUG COSM. L.J. 165, 165 (1989)).

³⁵ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996) (citation omitted).

³⁶ HUTT, MERRILL & GROSSMAN, *supra* note 5, at 992.

hearing aids.³⁷ When Congress enacted the MDA, it recognized that conflicting state and federal requirements would unduly burden the interstate trade of medical devices.³⁸

Therefore, the MDA was drafted with an express preemption clause, enabling federal regulation to trump state regulation of medical devices.

Rather than delineating the contours of the new divide between the state and federal device regulatory regimes, however, the MDA preemption clause became a source of vigorous debate. The following paragraphs will discuss the preemption clause and its ambiguities, and illustrate early understanding (or misunderstanding) of how federal preemption was meant to operate.

The preemption clause of the MDA states, in relevant part, that:

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.³⁹

The clause appears to be an express Congressional mandate that federal regulations will trump state regulations in the realm of medical device law.⁴⁰ Federal preemption of state law is a principle that derives from the Supremacy Clause within Article VI of the Constitution. Stated simply, when state law comes into conflict with federal law, federal law will supersede.⁴¹ This might seem to conflict with the traditional notion of state sovereignty. To protect the power of the states, therefore, courts have adopted a presumption *against*

³⁷ David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 104 (2005) (citations omitted).

³⁸ H.R. REP. NO. 94-853, at 45 (1976).

³⁹ 21 U.S.C. 360k(a) (2000); FDCA § 521(a).

⁴⁰ Note that the Act allows FDA to explicitly grant exemptions to state requirements that would otherwise be preempted by the MDA, and the process by which it does this is governed by 21 U.S.C. § 360k(b) (2000) and 21 C.F.R. § 808.1 (2006).

⁴¹ Article VI establishes the law of the United States as “the supreme Law of the Land...any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. CONST. art. VI, cl. 2.

preemption of state police power regulations in the absence of clear Congressional intent.⁴²

In this paper, our major question is whether the MDA was intended to preempt state common-law tort actions, like the one our John Doe wants to bring.

To determine whether state common-law tort claims are preempted by an express preemption clause, courts will first examine the language of the statute. At a glance, the text may seem clear, but it is actually rife with ambiguities that incited great debate within the judiciary. First, and most crucially, what does “requirement” mean? The MDA’s preemptive power only operates in the face of state “requirements.” This could refer only to “positive state law – that is, commands imposed by state statutes or duly promulgated state regulations that carry the force of law.”⁴³ Conversely, the term may be read more broadly, encompassing “state tort and damages law, which, through serial jury verdicts, could also be said to impose ‘requirements.’”⁴⁴ The interpretation of this one word means a world of difference for consumers or manufacturers. The narrower reading would allow injured consumers greater access to state courts and they could sue manufacturers for violations of common-law duties. The broader reading could virtually immunize manufacturers from being haled into state courts. This crucial inquiry is at the heart of preemption cases even outside the scope of the MDA, but it is especially the focus of the two Class III medical device cases that will be discussed at length in this paper – *Medtronic v. Lohr* and *Medtronic v. Riegel*.

An understanding of the word “requirement” is just not important in terms of assessing the state regulation in question. Recall that federal preemption only operates when state regulations differ from “any requirement applicable under [the MDA] to the device.”

Are PMA review and its abbreviated counterpart in section 510(k) on equal footing as federal

⁴² The Supreme Court “start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

⁴³ Vladeck, *supra* note 37, at 98.

⁴⁴ *Id.*

“requirements” applicable to medical devices under the MDA? As it would later turn out, the difference between these two processes would have a huge impact on the scope of federal preemption.

There is some obscurity inherent in the use of the “different from, or in addition to” language. A functionalist reading might counsel extending the MDA’s preemptive reach when state requirements attempt to impose *more* stringent regulations on a medical device, or when it would be impossible for a manufacturer to comply with both federal and state regulations. However, a literalist would say that state requirements are preempted even when they require *less* than federal law does, because this would theoretically make the state requirements “different from” the federal regime.

Finally, how do we determine when a state requirement “relates to the safety or effectiveness” of a medical device? Narrowly read, this could mean that the state requirement must specifically address the device or the category of medical devices. If read broadly, however, even a state requirement that applies generally, such as a duty sounding in tort or property, could be viewed as “relating to” devices if it happened to sweep medical devices into its reach.

Before we delve into how courts attempted to resolve these disputes, let us examine how Congress and FDA viewed the scope of MDA preemption.

(i) Scope of Preemption: Congressional Intent

Because of the strong presumption against federal preemption in the absence of clear Congressional intent, it is important to consider what Congress actually wanted the scope of the MDA preemption clause to be when it was drafted. The existence of an express preemption clause indicates that the federal government did intend to preempt at least some conflicting state or local regulatory measures.

The legislative history that accompanied the MDA briefly discussed the preemption

provision, saying that “if a substantial number of differing requirements applicable to a medical device [were] imposed by jurisdictions other than the Federal Government, interstate commerce would be unduly burdened.”⁴⁵ This strongly suggested that Congress intended to unify and standardize the regulation of medical devices under the federal scheme.

At the same time, however, Congress did explicitly authorize FDA to grant exemptions from federal preemption to some state and local regulations,⁴⁶ and this indicates that some overlap between state and federal regulation of devices was tolerable. In the legislative history of the MDA, it seemed apparent that Congress “sought to prevent medical device manufacturers from being exposed to conflicting requirements by the states and the federal government,” but that state requirements could be exempted from preemption provided that they were “compatible with the federal regulatory scheme.”⁴⁷

The major question that went unanswered both in the text of the preemption clause and in the legislative history accompanying it was: how did Congress intend to treat state tort actions? Prior to the enactment of the MDA, injured individuals could and did bring state law damages actions against medical device manufacturers. Indeed, the sheer magnitude of state tort claims filed against the manufacturer of the Dalkon Shield drove the company into bankruptcy.⁴⁸ Congress was thus certainly aware of the existence and prevalence of state tort litigation over medical devices when it drafted the MDA. Does its silence suggest that it intended to leave state tort law as a permissible status quo? Or would it have explicitly addressed this in the House and Senate Reports if it intended to save such claims from preemption?

Consider also the fact that the MDA contains a “savings clause,” which provides that:

⁴⁵ Carrier, *supra* note 33, at 551 (citing H.R. REP. NO. 94-853, at 45 (1976)).

⁴⁶ 21 U.S.C. § 360k(b) (2000); FDCA § 521(b).

⁴⁷ Carrier, *supra* note 33, at 552.

⁴⁸ Vladeck, *supra* note 37, at 103 (internal citation omitted).

“[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.”⁴⁹

Although this clause is not found in the same section as the preemption provision, there are commentators who believe that its language, especially the reference to damages being awarded for economic loss, suggests that Congress did not intend to preempt *all* common-law actions.⁵⁰

(ii) *Scope of Preemption: FDA Interpretation*

Despite the absence of clear Congressional intent in either the statute or the accompanying legislative history, we do have some evidence of what the agency charged with enforcing the MDA thought the scope of preemption would be. After the MDA was enacted, FDA promulgated regulations governing the preemption clause and detailing how states and localities could petition for exemptions.⁵¹ In the language of its regulations, FDA clarified the “any requirement” wording of the preemption clause as follows:

no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (*whether established by statute, ordinance, regulation, or court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.⁵²

This language, on its face, would seem to suggest that state tort remedies would be preempted under the MDA because they generate “court decisions.” However, FDA did not mean the language to be read so literally. Rather, the term “‘court decision’...apparently was intended only to address ‘judicial . . . *interpretations*’ of the relevant ‘statute, rule, or

⁴⁹ 21 U.S.C. § 360h(d) (2000); FDCA § 518(d).

⁵⁰ Roger W. Bivans, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 TEX. L. REV. 1087, 1094 (1996).

⁵¹ 43 Fed. Reg. 18,665 (May 2, 1978) (final rule amended by 45 Fed. Reg. 67,336 (Oct. 10, 1980) (codified at 21 C.F.R. § 808.1) (1994)).

⁵² 21 C.F.R. § 808.1(b) (1994) (emphasis added).

regulation.’’⁵³ The agency’s primary concern was not that a court decision would constitute a “requirement,” but instead that a court would interpret pre-existing, permissible state or local requirements in such a way that would bring them into conflict with federal regulation. FDA also explicitly stated that the MDA would not preempt state or local requirements “of general applicability that relate only incidentally to medical devices . . . [such as] the Uniform Commercial Code warranty requirements.”⁵⁴ Commentators have interpreted the FDA’s position to mean that common-law tort awards were similarly not preempted⁵⁵ even though the agency’s choice of language to communicate that may have been “unfortunate.”⁵⁶

The FDA regulations also illustrate that the agency thought state and local regulations were preempted “only when [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.”⁵⁷ This is an important aspect because it means that the MDA preemption clause would only operate when a given device was subject to regulations promulgated by FDA. This hearkens back to the debate over what level of regulation counts as an FDA “requirement” – another issue with which courts would struggle.

(iii) Scope of Preemption: The Courts Speak

In short, the MDA preemption clause had broad, ambiguous language that could be read to preempt state common-law tort actions. Congressional intent was difficult to discern from the record. The FDA regulations interpreting the MDA could easily be read to support preemption of state tort cases, even though FDA insisted it did not interpret the statute as such. In spite of (or perhaps because of!) FDA’s oddly worded regulations, the late 1980s

⁵³ Carrier, *supra* note 33, at 553 (citing 42 Fed. Reg. 30,383, 30,385 (June 14, 1977) (preamble to the proposed rule)) (emphasis added).

⁵⁴ 42 Fed. Reg. 30,834 (June 14, 1977).

⁵⁵ See, e.g. Vladeck, *supra* note 37, at 123; Carrier, *supra* note 33, at 553.

⁵⁶ See, e.g. Carrier, *supra* note 33, at 553.

⁵⁷ *Id.* at 554 (citing 1 C.F.R. § 808.1(d)).

and early 1990s generated high-profile court cases that found state tort awards to be preempted by the MDA.⁵⁸ At the same time, this viewpoint was not the clear consensus within the judiciary, and preemption defenses were rare.⁵⁹ For many years, the Supreme Court generally hesitated to find that federal public safety statutes preempted state tort law actions.⁶⁰ The Court also expressed that the “regulation of health and safety [was] historically an aspect of state police powers and thus a local concern.”⁶¹ Prior to 1992, therefore, the lower courts were mired in confusion about exactly how broad preemption under the MDA was really intended to be. It was the Supreme Court’s decision in *Cipollone v. Liggett Group*⁶² that finally opened the floodgates.⁶³

In 1992, the *Cipollone* Court addressed the preemption debate under a different federal statutory scheme – the Public Health Cigarette Acts of 1965 and 1969.⁶⁴ This field shared one key trait with the MDA – the use of the term “requirements” in a statutory provision that expressly preempted state law.⁶⁵ In interpreting this crucial word, the Court adopted a very broad reading that encompassed more than positive law. They held that the “phrase ‘no requirement...’ sweeps broadly and suggests *no distinction between positive*

⁵⁸ See *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D.In. 1988); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (citing language in FDA regulations to support the interpretation that the term “any requirement” as used in the preemption clause of the MDA includes court decisions).

⁵⁹ Vladeck, *supra* note 37, at 106.

⁶⁰ See, e.g. *Silkwood v. Kerr-McGee Corp.* 484 U.S. 238 (1984) (holding that even though Congress had occupied the field of nuclear safety, a state damages award for injuries suffered when plutonium escaped from a federally licensed power plant was not preempted). See also Robert Adler & Richard Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 914 (1994) (noting courts’ traditional caution in finding preemption of tort claims).

⁶¹ James P. Walsh, *Niehoff v. Surgidev Corp.: No Preemption of Kentucky Tort Law Claims by the Federal Medical Device Amendments*, 25 N. KY. L. REV. 615, 624-25 (1998) (citing *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985)).

⁶² 505 U.S. 504 (1992).

⁶³ Prior to the case, it was a rarity for device manufacturers to raise preemption defenses in state tort suits; afterwards, they did so routinely. Vladeck, *supra* note 37, at 106.

⁶⁴ 15 U.S.C. 1331 – 1340.

⁶⁵ The 1969 Act referred to “requirements or prohibitions...imposed under State law.” *Cipollone*, 505 U.S. at 520 (quoting § 5(b) of the 1969 Act).

enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.”⁶⁶ This holding opened the door for a very broad reading of preemption under the MDA and thus “unleashed a torrent of preemption litigation.”⁶⁷ The use of the preemption defense in the lower courts became routine.⁶⁸

After *Cipollone*, state and federal courts were fairly unanimous in finding that tort claims brought by plaintiffs allegedly injured by medical devices were preempted under the MDA’s express preemption clause.⁶⁹ Most of these courts reasoned that because the MDA preemption clause contained the same “requirements” language as that of the federal statute in *Cipollone*, then state law tort claims which imposed requirements “different from, or in addition to”⁷⁰ federal requirements for medical devices were clearly preempted.⁷¹ A handful of courts, however “refused to construe the MDA’s preemption provision so broadly and found that only some state law claims were preempted, or even that no claims were preempted at all.”⁷²

Because of the conflict surrounding the preemptive scope of the MDA, the Supreme Court granted certiorari to an Eleventh Circuit case in 1996,⁷³ and the resulting decision

⁶⁶ *Cipollone*, 505 U.S. at 521.

⁶⁷ Vladeck, *supra* note 37, at 106.

⁶⁸ *Id.*

⁶⁹ Walsh, *supra* note 61, at 627 (citing Robert Adler & Richard Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 917 n.108 (1994)) (noting the unanimous post-*Cipollone* finding of preemption among the courts, and citing numerous cases).

⁷⁰ 21 U.S.C. § 360k(a) (1994).

⁷¹ See *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 851-52 (Mo.1996) (discussing *Cipollone* analysis and noting federal appellate court cases which followed the *Cipollone* definition of requirements to hold that the MDA preempted most state common-law claims).

⁷² Walsh, *supra* note 61, at 628 (citations omitted). See Anne-Marie Dega, *The Battle over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims?* 27 LOY. U. CHI. L. J. 615, 639-47 (1996) (discussing minority partial preemption and no preemption court decisions and citing several cases).

⁷³ *Medtronic, Inc. v. Lohr*, 56 F.3d 1335 (11th Cir. 1995), *aff’d in part and rev’d in part*.

would become a controlling precedent in the field of medical device litigation. This case was *Medtronic v. Lohr*.⁷⁴

Part II: *Medtronic v. Lohr*

In *Medtronic v. Lohr*, the Supreme Court addressed the specific issue of federal preemption of state tort suits involving Class III medical devices under the MDA.

Lora Lohr was a cardiac patient in need of a pacemaker. In 1987, she was implanted with a Medtronic device that contained one of the company's Model 4011 pacemaker leads.⁷⁵ Medtronic had taken advantage of FDA's expedited section 510(k) process when it introduced the Model 4011 lead onto the market. The lead was approved because it was "substantially equivalent" to devices already being lawfully sold. A few years after Lohr received the pacemaker, the device failed, resulting in a cardiac crisis that led to emergency surgery. Lohr's physician attributed the failure to a defect in the lead.⁷⁶ Lohr and her husband filed a complaint containing a negligence count and a strict liability count in Florida state court.⁷⁷

The Lohrs alleged that Medtronic was negligent in the design, manufacture, and sale of the pacemaker. To support their strict liability claim, they argued that the device was defective and unreasonably dangerous to foreseeable users at the time of its sale.⁷⁸ Medtronic removed the case to federal district court and moved for summary judgment, asserting that the Lohrs' claims were preempted by 21 U.S.C. § 360k(a) – the MDA preemption clause.⁷⁹ The district court denied Medtronic's motion, but shortly thereafter, the

⁷⁴ 518 U.S. 470 (1996).

⁷⁵ "The lead is the portion of a pacemaker that transmits the heartbeat-steadying electrical signal from the 'pulse generator' to the heart itself." *Id.* at 480.

⁷⁶ *Id.* at 480-81.

⁷⁷ *Id.* at 481.

⁷⁸ *Id.* (citations omitted).

⁷⁹ *Id.*

Eleventh Circuit Court of Appeals concluded that the statute required preemption of at least some common-law claims brought against the manufacturer of a medical device.⁸⁰ The case was volleyed back to the district court, which dismissed the Lohrs' complaint, but upon its return to the Court of Appeals, the Eleventh Circuit debated the language of the preemption clause, the meaning of the word "requirement," and the fact that the medical device in question had undergone only the cursory section 510(k) review process. The Appeals Court concluded that the Lohrs' design-based claims (alleging design defect under a negligence theory or unreasonable danger under a strict liability theory) were not preempted because an FDA finding of "substantial equivalence" was not sufficient to classify as a federal "requirement" triggering the preemption clause of the MDA. Recognizing that the Circuits were divided over the scope of MDA preemption of state common-law claims, the Supreme Court took the case.

Rather than resolving the myriad confusing issues in this field, *Medtronic v. Lohr* gave us a fractured holding and may have raised just as many questions as it answered.⁸¹ To streamline our discussion of the case, this paper will address the Court's holdings under the following headings: (A) does the preemption clause of the MDA apply to state common-law tort actions? (B) does preemption under the MDA apply to *this* case involving a Class III medical device that underwent FDA's section 510(k) review?

(A) Does the preemption clause of the MDA apply to state common-law tort actions?

The short answer to this question is: yes. The Supreme Court did not repudiate its finding in *Cipollone* that the word "requirement" could extend outside the realm of positive

⁸⁰ *Id.* at 482-83.

⁸¹ *Lohr* consists of an opinion by the Court (authored by Justice Stevens, and joined by Justices Kennedy, Souter, Ginsburg, and Breyer), a plurality opinion (authored by Justice Stevens and joined by Justices Kennedy, Souter, and Ginsburg), a concurrence (authored by Justice Breyer), and a partially concurring/partially dissenting opinion (authored by Justice O'Connor and joined by Justices Rehnquist, Scalia, and Thomas).

law and encompass common-law tort claims. It did, however, limit the sweeping reach of *Cipollone* within the context of the MDA to hold that only *some* state common-law tort claims might be preempted.

The Court cited *Cipollone* for its approach to the preemption question.⁸² The express presumption clause of the MDA indicated that Congress intended to preempt at least some state law, but the Court needed to conduct further analysis to determine the “domain expressly pre-empted” by its language.⁸³ In doing this, the Court restated two primary presumptions: 1) “that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress”⁸⁴ and 2) that “the scope of a pre-emption statute must rest primarily on ‘a fair understanding of congressional purpose.’”⁸⁵ This led the Court into an analysis of Congressional intent during the drafting of the MDA.

The Court found implausible Medtronic’s argument that all common-law causes of action were “requirements” that would impose duties “different from, or in addition to” general standards promulgated by FDA. They focused on the term “requirement” itself, saying that “if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it.”⁸⁶ The Court distinguished *Cipollone* (in which it had found that a statute preempting state “requirements” could also preempt common-law damages claims) by saying that a similar reading of the MDA would be overbroad. The statutes at issue, after all, were different. The Court was convinced that when Congress enacted the MDA, it was more worried about specific, conflicting positive state law, rather

⁸² Lohr, 518 U.S. at 484.

⁸³ *Id.* at 484 (citing *Cipollone*, 505 U.S. at 517 (1992)).

⁸⁴ *Id.* at 485 (citing *Rice v. Santa Fe Elevator Corp.* 331 U.S. at 230 (1947)).

⁸⁵ *Id.* at 485-86 (citing *Cipollone*, 505 U.S. at 530 n.27 (opinion of Stevens, J.)).

⁸⁶ *Id.* at 487.

than the more general regulatory influence of common-law tort actions.⁸⁷ The Court also found that the basic purpose of the MDA was to promote safety and effectiveness of medical devices, and a broad reading of state tort preemption would contravene Congressional intent here.⁸⁸ Finally, the legislative history of the MDA convinced the Court that Congress could not have intended a sweeping preemptive reach. After all, it had been well aware of ongoing lawsuits in the medical device arena at the time. Thus, if the legislation was intended to suppress all these claims in future, it was “spectacularly odd” that no mention was made of such drastic reform in the debates.⁸⁹

The Lohrs wanted the Supreme Court to say that common-law duties would never be “requirements” within the meaning of § 360k(a) (thus cutting even further back on *Cipollone*), but the Court refused to reach this holding because they were able to find the Lohrs’ claims not preempted without going that far.⁹⁰ While all acknowledged that some common-law duties in future cases might be preempted, the justices disagreed on exactly how much preemption was intended. The plurality opinion took into account the MDA’s language and history to find that the statute was not intended to preempt most damages actions.⁹¹ This opinion stated that “given the critical importance of device specificity in our (and the FDA’s) construction of § 360k(a), it is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has ‘the effect of establishing a substantive requirement for a specific device.’”⁹² On the other hand, Justice Breyer stated in his concurrence that he was “not convinced that future incidents of MDA pre-emption of common-law claims [would] be

⁸⁷ *Id.* at 489.

⁸⁸ *Id.* at 490.

⁸⁹ *Id.* at 491.

⁹⁰ *Id.* at 502.

⁹¹ *Id.* at 491.

⁹² *Id.* at 502-03.

‘few’ or ‘rare.’”⁹³ The dissenters criticized the Court for relying on FDA interpretations of the statute in a context where agency deference was unwarranted and shared Justice Breyer’s doubts about whether future preemption would be “rare.”⁹⁴

In summary, the Court found that some state common-law tort claims may be preempted under the MDA, but left us with little concrete guidance as to exactly how much tort law this decision would subsume.

(B) Does preemption under the MDA apply to this case involving a Class III medical device that underwent FDA’s section 510(k) review?

The Court found that the Lohrs’ claims in this case were not preempted. In order to reach that holding, they gave three major reasons for what would “rescue” a state common-law tort action from the reach of § 360k(a). The crucial factors were: (i) the specificity of federal regulations, (ii) the specificity of state regulations, and (iii) whether state duties paralleled federal ones.

(i) Specificity of federal regulations

The Eleventh Circuit had found the Lohrs’ defective design claims *not* preempted because the device had undergone the section 510(k) approval process before going on the market. The Court of Appeals reasoned that because the section 510(k) process only involved FDA determination of the product’s “substantial equivalence” to something already on the market, it did not constitute a review of safety and effectiveness, and was thus not sufficiently concrete to constitute a “pre-empting federal requirement.”⁹⁵ The Supreme Court agreed with this reasoning, deducing that the section 510(k) process would allow some

⁹³ *Id.* at 508.

⁹⁴ *Id.* at 511-12. The dissenting justices believed the MDA was clear enough on its face and strongly criticized the importation of FDA’s “narrowing” regulations into the determination of preemptive scope.

⁹⁵ *Id.* at 492.

potentially risky devices onto the market without ever having undergone formal review.⁹⁶

The Court indicated that the word “requirements” in § 360k(a) carried some weight.

Basically, in order for the MDA preemption clause to be triggered, a medical device manufacturer would need to show that it operated in a realm in which the federal government had imposed regulations on it that would make being subjected to potentially conflicting state requirements in a common-law tort action unfair.

The section 510(k) process was deemed inadequate to trigger the MDA preemption clause. As the Court said, FDA “did not ‘require’ Medtronics’ [sic] pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process.”⁹⁷ The Court found that while Congress had pragmatic reasons for setting up the section 510(k) process, it did not manifest any intent to shield device manufacturers that took advantage of this system from having to defend themselves against state law claims of negligent design.⁹⁸ A mere finding of “substantial equivalence” does not equate to a federal “requirement” for the purposes of § 360k(a).

The Lohrs also brought claims alleging that Medtronic had failed to comply with manufacturing and labeling duties under Florida common law. The Court of Appeals had found these claims to be preempted because of the existence of supposedly countervailing federal “requirements.” FDA has promulgated general requirements that apply to all medical devices. These are called “Good Manufacturing Practices” or “GMPs” and all device manufacturers must comply with them.⁹⁹ The Court of Appeals found the Lohrs’

⁹⁶ “If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.” *Id.* at 493 (quoting Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L. J., 511, 516 (1988)).

⁹⁷ *Id.* at 493-94.

⁹⁸ *Id.* at 494.

⁹⁹ *Id.* at 513-14; 21 C.F.R. §§ 820.20-820.198 (1995).

manufacturing and labeling claims to be preempted because they thought that subjecting manufacturers to state standards that would potentially differ from the GMPs would “interfere with the consistent application of general federal regulations governing the labeling and manufacture of all medical devices.”¹⁰⁰ The Supreme Court, however, hinged its analysis on the *specificity* of the applicable federal “requirements.” The MDA preemption clause specifically states that a federal requirement must be “applicable to the device” in question. GMPs are of such a general nature that, like the section 510(k) process, the Court found them insufficient to trigger the preemption clause.¹⁰¹ The Court found its reasoning to be supported by the FDA regulations, which say that state requirements are preempted only when FDA has established “specific counterpart regulations or...other specific requirements applicable to a particular device.”¹⁰²

In short, a majority of the *Lohr* Court found that a medical device needed to be subject to *specific* federal requirements in order to trigger a preemption analysis. The Court admitted that if FDA had subjected the Model 4011 lead to more rigorous review, such as PMA, this would have been a much harder case to decide.¹⁰³

(ii) *Specificity of state regulations*

A majority of the Court believed that in order to be susceptible to federal preemption, a state requirement must have something other than mere “general applicability” and must be developed “with respect to” a particular medical device.¹⁰⁴ The Court found support for this finding in the FDA regulations, which state that “pre-emption [should] occur only where a *particular* state requirement threatens to interfere with a *specific* federal interest.”¹⁰⁵ We

¹⁰⁰ *Lohr*, 505 U.S. at 497.

¹⁰¹ *Id.* at 498

¹⁰² *Id.* at 498; 21 CFR § 808.1(d)(1995).

¹⁰³ *Lohr*, 505 U.S. at 493-94.

¹⁰⁴ *Sayler & Thomas*, *supra* note 22, at 199.

¹⁰⁵ *Lohr*, 505 U.S. at 500 (emphasis added).

have already discussed the need for specificity in the countervailing federal requirements,¹⁰⁶ but now we see that the Court will look for specificity in the state requirements as well.

The FDA regulations indicate that state requirements of “general applicability” are not preempted unless they have “the effect of establishing a substantive requirement for a specific device.”¹⁰⁷ The Court held that state requirements worthy of preemption are those developed “with respect to” medical devices and that are “different from, or in addition to” applicable federal requirements.¹⁰⁸

Basically, the MDA will likely not preempt state requirements that apply generally to all products on the market. For example, suppose a state law was generally applicable to all products sold in pharmacies or supermarkets and it encompassed a medical device within its sweep. Since this regulation would be one of “general applicability” and that was not developed “with respect to” the device, it would likely be found too non-specific to trigger MDA preemption.¹⁰⁹ The MDA will likely preempt state requirements that pertain specifically to medical devices and that come into conflict with existing federal regulations. For example, suppose a state law purported to impose a safety standard on a medical device even though FDA had already promulgated safety requirements for that product. This regulation would be a state requirement specific to the device in question and if it was “different from, or in addition to” FDA standards, it would likely trigger the preemption clause.

One outcome of *Lohr* is the implication that courts will look for specificity in both the federal requirements and the state requirements in order to decide whether preemption under

¹⁰⁶ See *supra* Part II(B)(i).

¹⁰⁷ 21 C.F.R. § 808.1(d)(6)(i) (1995).

¹⁰⁸ *Lohr*, 505 U.S. at 500.

¹⁰⁹ Or would it? See *infra* Part IV(B) for a discussion of *Medtronic v. Riegel*, in which the Court significantly cut back on this analysis of state requirement specificity.

the MDA is triggered. The Court projected that this would likely entail a fact-specific inquiry, involving “careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.”¹¹⁰

(iii) *Parallel duties in state and federal law not preempted*

The Court also clarified the ambiguous “different from, or in addition to” language of § 360k(a) in its holding. Some of the Lohrs’ claims were based on Florida law that would have imposed common-law duties that merely duplicated existing requirements under federal law. For example, the Court acknowledged that an examination of the Lohrs’ negligence claim might involve an inquiry into whether there was negligent conduct or unreasonable hazard created by Medtronic in producing and distributing the Model 4011 lead. Subjecting Medtronic to this analysis might mean that they would literally face “additional” elements of a state law cause of action, but the Court found that these made the state requirements *narrower*, not broader than the federal regulations. The Court was dismissive of an overly literal reading of § 360k(a), and stated that: “[w]hile such a narrower requirement might be ‘different from’ the federal rules in a literal sense, ‘such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule.’”¹¹¹ Essentially, the Court found that subjecting manufacturers to state requirements that ran parallel to federal requirements would not create the type of state/federal conflict that runs amok of the preemption principle. Instead, allowing such claims would merely give

¹¹⁰ Lohr, 505 U.S. at 500. Not all the justices agreed with this “specificity” focus though. The dissenters clung tightly to the logic of *Cipollone* in stating that the language of the MDA was clear enough on its face. They heavily criticized the other justices’ searching inquiries beyond the text of § 360k(a) into Congressional intent and FDA regulations. According to these justices, “[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on ‘any requirement’ exists.” *Id.* at 512 (O’Connor, J., dissenting). These justices would have supported a more general understanding of “requirement” based solely on the text of the MDA.

¹¹¹ *Id.* at 495.

manufacturers more of a reason to comply with identical existing requirements under federal law, and would thus enhance the effectiveness of the federal regulatory scheme. The Court found support for this holding in the regulations promulgated by FDA, which state that § 360k(a) “does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.”¹¹² In short, common-law actions based on state requirements that merely replicate federal laws will survive preemption under the MDA.

The overarching message of *Medtronic v. Lohr* is that federal preemption under the MDA will occur “where a particular state requirement threatens to interfere with a specific federal interest.”¹¹³ This entails a determination of particularity, or specificity, of both the state and federal requirements in question, and it entails a finding that the state requirements do not merely replicate obligations under federal law. After years of lower court conflict surrounding the reach of the MDA’s preemption clause, *Lohr* had a real opportunity to provide concrete answers, and it did, to some extent. One clear application of this case will be to lawsuits involving medical devices that have only undergone section 510(k) review as a precondition to marketing.¹¹⁴ It seems clear now that these manufacturers will not be able to raise the MDA preemption defense in state common-law tort actions. This is significant because, as discussed previously, the vast majority of devices on the market have only undergone this cursory review. At the same time, the decision also answered the question of

¹¹² *Id.* at 496-97 (quoting 21 C.F.R. § 808.1(d)(2) (1995)). Note that even the dissenters agree that parallel claims should survive preemption: “Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is ‘different from, or in addition to,’ requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. *Section 360k* does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.” *Lohr*, 505 U.S. at 513.

¹¹³ *Lohr*, 505 U.S. at 500.

¹¹⁴ By extension, this case also suggests that Class I and Class II medical devices fall within the same rubric since they are only subject to very general federal requirements, such as GMPs, which were specifically found to be insufficient to trigger MDA preemption here.

whether the reasoning of *Cipollone* would apply to the MDA context – we now know that at least *some* state common-law claims could fall within the preemptive scope of § 360k(a).

In the aftermath of the decision, many commentators questioned the Court’s reasoning and the wisdom of its holding, and criticized the gaps that still remained in our understanding of the MDA’s preemptive framework. What would *Lohr* mean for devices that had undergone the PMA or IDE process? How “rare” would preemption of state common-law tort claims turn out to be? How “specific” would a conflicting state “requirement” have to be to trigger the preemption clause? How would the lower courts respond? In Part III, we turn to the aftermath of *Medtronic v. Lohr* and the continuing confusion that eventually led to the Court stepping in again in *Medtronic v. Riegel*.

Part III: Preemption under the MDA in the Years between *Lohr* and *Riegel*

In *Lohr*, all the justices agreed that common-law damages claims might be preempted under the MDA. However, the fractured nature of the holding left us with some confusion as to the *extent* to which state common-law claims would be preempted in future. Recall that four justices believed that the MDA was “not intended to pre-empt most, let alone all general common-law duties enforced by damages actions.”¹¹⁵ Five justices expressed a more expansive conception of which claims would be preempted. Breyer’s concurrence indicated that he was “not convinced that future incidents of MDA pre-emption of common-law claims [would] be ‘few’ or ‘rare’”¹¹⁶ and the dissenters openly advocated a much broader reading of the scope of preemption than the plurality expressed.¹¹⁷ This fundamental disagreement between the justices made it difficult to predict exactly which types of cases would be preempted in the post-*Lohr* world.

¹¹⁵ *Lohr*, 505 U.S. at 491.

¹¹⁶ *Id.* at 480 (Breyer, J., concurring).

¹¹⁷ *Id.* at 509 (O’Connor, J., dissenting).

After *Lohr*, there were those commentators who criticized the Court's *Cipollone*-inspired belief that Congress intended the word "requirements" in the MDA to subsume state common-law tort actions at all. As there is a presumption against preemption unless Congressional intent is clear and manifest, *Lohr* could be viewed as a misconstruction of intent in the face of ambiguous language.¹¹⁸ The response from the FDA certainly seemed to indicate disapproval of the Court's decision.

(A) *The FDA Responds to Lohr*

In the wake of the *Lohr* decision, FDA published its interpretation of the holding and addressed circumstances when the agency believed state requirements might fall within the preemptive scope of § 360k(a).¹¹⁹ While FDA had historically refrained from expressing an opinion on private product liability suits, it felt that it needed to address the issue in light of the landmark ruling. FDA embraced a narrow reading of the express preemption clause and stated that in order for a duty under state law to be vulnerable to preemption, "it must differ from or add to a 'requirement' [the agency] had already prescribed for the particular type of device."¹²⁰ General duties applicable to all devices or to a class of devices would not be preempted.¹²¹

FDA's interpretation "essentially neutered [§ 360k(a)] as a source of limitation on state tort law."¹²² It also had the unfortunate effect of removing from the MDA's preemptive scope situations to which § 360k(a) was clearly *supposed* to apply. Commenters pointed out that FDA's newly stated view would allow states to require and deny pre-market approval for

¹¹⁸ See, e.g., Vladeck, *supra* note 37, at 112-13.

¹¹⁹ 62 Fed. Reg. 65384 (Dec. 12, 1997).

¹²⁰ HUTT, MERRILL & GROSSMAN, *supra* note 5, at 1489.

¹²¹ The agency went on to declare that a "requirement" must appear in a regulation duly promulgated in the Federal Register or must be imposed by an administrative order that was the product of a formal adjudicatory proceeding involving a specific device. No other duties or conditions that FDA might impose would constitute "requirements" for purposes of § 360k(a). *Id.*

¹²² *Id.*

devices that FDA had already approved. This would unquestionably contravene the underlying purpose of the MDA and eviscerate the Court's holding in *Lohr*. As a result, FDA withdrew the notice just over a year later.¹²³

FDA's response to the case was confusing, at best. It seemed to indicate the desire to reinstate some protection for state tort law claims. The agency, however, was unable to tailor its language narrowly enough to promote consistency with *Lohr* and the goal of protecting federal interests. Aside from the mixed signals sent by the agency, the post-*Lohr* period would be further complicated by general trends in the Supreme Court's preemption doctrine based on other cases involving comparable federal statutes and regulatory schemes.

(B) Trends in Preemption in the Post-Lohr period

The Supreme Court had half-opened the door to preemption of state common-law damages claims in *Cipollone*. Then, it had extended that reasoning to half-open the door to preemption under the MDA in *Lohr*. However, the cases the Court decided in the post-*Lohr* years generated some uncertainty as to the general direction that preemption of state common-law claims would take next.¹²⁴

In 2000, the Court decided *Geier v. American Honda Motor Co.*¹²⁵ This case involved regulations promulgated under a federal law governing motor vehicle safety – the National Traffic and Motor Vehicle Safety Act of 1966.¹²⁶ The Act contained a preemption provision and a savings clause, much like the MDA. In this case, a driver collided with a tree and suffered serious injuries. Her Honda vehicle did not have an air bag, and she sued the

¹²³ *Id.* at 1489-90; 63 Fed. Reg. 39789-01 (July 24, 1998).

¹²⁴ See generally Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, B.C. L. REV. 1089, 1124-1134 (1997) (discussing post-*Lohr* preemption trends in the Supreme Court).

¹²⁵ 529 U.S. 861 (2000).

¹²⁶ 15 U.S.C. 1392(d) (1988) (current version at 49 U.S.C. 30103(b) (2000)). The regulations were promulgated by the Department of Transportation pursuant to the authority of the Act, and they were referred to as the Federal Motor Vehicle Safety Standards ("FMVSS").

manufacturer in state court, alleging defective design. The preemption issue was relevant because existing federal safety standards specifically permitted manufacturers to choose between air bags and seat belt systems. The Court found this state tort suit preempted because it would subject the manufacturer to differing requirements under federal and state law, and would frustrate the purpose of the federal regulatory scheme. However, Justice Breyer, writing for the Court, echoed his analysis in *Lohr* and stated that the preemption clause did not indicate congressional intent to defeat *all* product liability claims, especially when the federal government had only established a minimum standard of safety.¹²⁷ *Geier* was an emphatic restatement of the importance of finding actual conflict between state and federal requirements in order to find preemption.¹²⁸

In 2001, the Court decided another case involving the MDA, but it was a narrow and fact-specific holding that did not do much to clarify the scope of preemption as much as one might like. In *Buckman v. Plaintiffs' Legal Committee*, the Court had to determine whether the MDA preempted a state action based on a defendant device manufacturer's fraudulent misrepresentations to FDA in order to obtain approval for orthopedic bone screws.¹²⁹ The Court found that a state law-based fraud-on-the-FDA claim would conflict with FDA's own authority and ability to police fraud against itself. This shed some light on another type of state common-law tort claim that would be preempted, but the holding had considerably limited reach or predictive value.

In 2002, the Court decided *Sprietsma v. Mercury Marine*, which involved preemption under the Federal Boat Safety Act of 1971 ("FBSA").¹³⁰ In this case, a woman was killed in a boating accident after being struck by the propellers on an outboard motor. Her husband sued the boat manufacturer in state court, alleging defective design. The manufacturer

¹²⁷ See *Geier*, 529 U.S. at 870.

¹²⁸ See *Davis*, *supra* note 124, at 1124-26.

¹²⁹ 531 U.S. 341, 350 (2001).

¹³⁰ 537 U.S. 51 (2002).

argued that the FBSA expressly preempted these common-law claims, especially in light of the fact that the Coast Guard (charged with promulgating federal regulations in this field) had explicitly decided *not* to require propeller guards. The language of the FBSA was similar to the MDA in its use of the word “requirement,”¹³¹ making this decision illustrative of which common-law claims the Court would treat as worthy of preemption. Writing for a unanimous Court, Justice Stevens disposed of the manufacturer’s express preemption defense. He stated that the clause was intended to apply to state or local positive laws, and that the language was “most naturally read as not encompassing common-law claims.”¹³² Any analogy between the FBSA and the MDA, however, must be made cautiously because, unlike the MDA, the FBSA did explicitly refer to a “law or regulation” in its preemption clause. However, in light of the fact that the clause went on to describe such laws and regulations as “imposing...requirement[s],”¹³³ the argument existed that this holding could counsel a narrower reading of tort claims triggering preemption under the MDA.

In 2005, the decision in *Bates v. Dow Agrosciences*¹³⁴ suggested that a majority of the Court held a narrow view of claims that common-law duties would be preempted. In this case, Texas farmers alleged that their crop had been damaged by defendant Dow’s weed killer, which had supposedly been promoted in a misleading manner. Plaintiffs sought damages under Texas law, and defendants argued that such a claim would be preempted because being subjected to damages in state court would force them to change their product labeling. This would have had the effect of imposing requirements “in addition to or

¹³¹ In relevant part, the FBSA preemption provision provided that “a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a *requirement* for associated equipment... that is not identical to a regulation prescribed [by the federal government pursuant to this Act].” 46 U.S.C. § 4306 (emphasis added).

¹³² *Sprietsma*, 537 U.S. at 63.

¹³³ 46 U.S.C. § 4306.

¹³⁴ 544 U.S. 431 (2005).

different from” federal ones, as stated in the preemption clause of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”).¹³⁵ Stevens, writing for the majority, rejected the argument that the preemption clause precluded enforcement of *any* common-law duty that might lead a manufacturer to make changes to a product label. The opinion stated that while *some* common-law duties might be included within the term “requirement,” such duties would need to “command conduct that went beyond or conflicted with the requirements [the federal government] imposed” in order to be preempted.¹³⁶ While making it clear that state requirements that would carry the force of law and compel obedience were likely to be preempted, the majority clarified that “an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”¹³⁷ Like *Sprietsma* before it, this case suggested a trend toward more protection for state common-law tort actions than one might have imagined in the immediate post-*Lohr* era.

In cases like *Cipollone* and *Lohr*, the Court had appeared to be cutting away at the protections that preemption doctrine had previously provided to state common-law damages actions. However, in the post-*Lohr* era, cases like *Sprietsma* and *Bates* granted favorable treatment to “the long-standing role of tort litigation in regulating public health and safety”¹³⁸ and they “emphasize[d] the concurrent role of the states in that regulation.”¹³⁹ Indeed, one commentator described *Bates* as “the Court...trying to put the *Cipollone* genie back in the bottle.”¹⁴⁰

Geier and *Buckman* seemed to at least suggest that the Court would continue to act carefully in finding state common-law actions preempted under federal statutes. *Bates* and

¹³⁵ The preemption clause of FIFRA states, in relevant part, that a state: “shall not impose or continue in effect any *requirements* for labeling or packaging in addition to or different from those required under this subchapter.” 7 U.S.C. § 136v(b) (emphasis added).

¹³⁶ HUTT, MERRILL & GROSSMAN, *supra* note 5, at 1490.

¹³⁷ *Bates*, 544 U.S. at 445.

¹³⁸ *Davis*, *supra* note 124, at 1133 (citing *Bates*, 544 U.S. at 449; *Sprietsma*, 537 U.S. at 70).

¹³⁹ *Id.*

¹⁴⁰ Vladeck, *supra* note 37, at 100.

Sprietsma suggested a reluctance on the Court's part to preempt state common-law tort actions when: (i) Congress was aware of a history of product liability litigation in the field prior to enacting a federal law, and (ii) preemption would deny protection to those injured by regulated conduct.¹⁴¹ In the context of the passage of the MDA, Congress definitely knew about pre-existing device litigation and yet it still did not use unmistakably clear language preempting state tort claims in the statute. Furthermore, the FDCA does not provide a private right of action.¹⁴² Perhaps future courts were supposed to be more cautious about preempting state causes of action that would leave injured plaintiffs without recourse. At the same time, these two cases did interpret other federal statutes, and that diminished their predictive weight in the medical device arena.

If the Supreme Court's softer treatment of common-law claims in the post-*Lohr* era seemed puzzling, at least it was far subtler than what FDA did next.

(C) FDA Changes its Mind

Recall that historically, FDA had shied away from issuing opinions on product liability suits at all. After *Lohr*, it responded with an anti-preemption publication, which, although later withdrawn, did suggest that the agency viewed many state tort claims as falling outside the scope of the MDA's preemption clause. In subsequent years, however, the agency did an about-face. As part of his "tort reform" campaign, President George W. Bush

¹⁴¹ Courts "must determine whether the common law duties imposed by state law are sufficiently direct and prescriptive to constitute 'requirements.' And courts must determine whether there was a history of product liability litigation over the regulated products prior to the enactment of federal law. If there was, as there was in *Bates*, then the Court thought that if Congress intended to deprive injured parties of pre-existing compensatory remedies, it would do so with unmistakable clarity." *Id.* (citations omitted).

¹⁴² The MDA does not explicitly say that Congress is seeking to nullify existing state damage claims, which have traditionally provided compensation to those injured by medical devices. Some federal statutes do explicitly eliminate the possibility of such claims, but they do so in unmistakable terms, and often have a federal remedy in lieu of the displaced state remedies. *See id.* at 98 n.16 (citing examples of federal statutes that provide statutory remedies when they explicitly preempt state tort actions).

pushed executive agencies to issue broad interpretations of preemption provisions in regulatory statutes.¹⁴³ FDA was “on the front line of this campaign, both reversing its longstanding view that the MDA preemption provision applies only in exceptional circumstances, and aggressively presenting its new pro-preemption views in court.”¹⁴⁴

This change of heart was surprising, but not necessarily determinative of how courts would respond. As a matter of administrative law, courts do not always necessarily owe deference to an agency’s view of the scope of a federal preemption clause (although the Court in *Lohr* did rely heavily on FDA regulatory language in defining “requirements”).¹⁴⁵ Additionally, even though FDA changed its publicly acknowledged position on preemption, it did not formally amend its regulations to reflect the change of heart. As a result, the agency’s official regulations still counseled narrow application of § 360k(a) amidst its pro-preemption publicity campaign.¹⁴⁶

(D) The Courts Respond Inconsistently

With the Supreme Court’s preemption jurisprudence counseling caution and FDA’s position on preemption changing entirely, it should come as no surprise that the lower courts responded inconsistently in deciding the scope of preemption of state common-law tort claims brought after *Lohr*.

¹⁴³ *Id.* at 121.

¹⁴⁴ *See id.* (citing example of *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004)). Vladeck also points out that in the post-Bush tort reform era, FDA has “accomplished a complete transformation of its position on the preemptive scope of the MDA and has actively solicited guidance from pharmaceutical and medical device firms about pending lawsuits in which [it] could participate to press its pro-preemption position.” *Id.* at 122 (citation omitted).

¹⁴⁵ When Congressional intent is clear in the statute itself, the Court does not owe an agency any deference in construing the law. It is only when a statute is ambiguous that a Court should accord weight to agency construction – a practice typically referred to as “Chevron deference.” *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). *See also Lohr*, 518 U.S. at 512 (O’Connor, J., dissenting) (criticizing the majority for according deference to FDA position on the scope of preemption under the MDA because, “[w]here the language of the statute is clear, resort to the agency’s interpretation is improper.”)

¹⁴⁶ *Id.* at 124-25.

Most courts had no trouble rejecting manufacturers' preemption defenses in cases where devices had only undergone section 510(k) review, as in *Lohr*.¹⁴⁷ Courts struggled more with deciding how *Lohr* was meant to apply to devices that had undergone the PMA or IDE process though, and differing results abounded.¹⁴⁸

Pro-plaintiff commentators praised *Lohr* as drastically diminishing the viability of the preemption defense for device manufacturers.¹⁴⁹ Pro-defendant commentators saw *Lohr*'s bark as worse than its bite, and thought its circumscribed application posed little threat to the medical device industry.¹⁵⁰ Based on the Court's heavy reliance on the cursory and status quo-preserving nature of the section 510(k) process in finding the *Lohr*'s claims not preempted, it seemed very possible that cases involving devices that had undergone the "rigorous, regulation-intensive, and device-specific PMA and IDE processes" might produce a different result.¹⁵¹ It quickly became clear that it would be appropriate and even necessary for the Supreme Court to hear a PMA case to clear up the confusion about what *Lohr* meant

¹⁴⁷ Sayler & Thomas, *supra* note 22, at 201 n.77 (listing string of post-*Lohr* cases that have rejected preemption defense).

¹⁴⁸ *Id.* at 202-04, n.89 (listing string of cases in which differing results were reached in cases where device in question had undergone PMA). *See also* Vladeck, *supra* note 37, at 99. ("The contours of the Court's ruling in *Medtronic* are unclear and hotly disputed, and there has been a flood of conflicting lower cases in *Medtronic*'s aftermath attempting to draw a line between those claims preempted by the MDA and those claims that are not preempted.")

¹⁴⁹ "In *Medtronic v. Lohr*, the Supreme Court gave control of common-law product liability lawsuits for defective medical devices back to the States, and effectively eliminated one of the only defenses left for medical device manufacturers. If the cost of defending these actions becomes prohibitively high, the practical result may be a halt in the advances in technology for medical devices. Additionally, the differing opinions of the Supreme Court in this case raise the question of when, if ever, common-law claims will be pre-empted in the future." Rosemary V. Bourne, *Medtronic v. Lohr: State Common-Law Claims Involving Class III Medical Devices Are Not Pre-Empted by The Medical Device Amendments Of 1976*, 27 U. BALT. L. F. 39, 41 (1996).

¹⁵⁰ "While the opinion's holding is adverse to defendants, its reach is suspect. The amount of attention devoted to the lenient nature of the section 510(k) process suggests that the holding warrants narrow application. Thus, the medical device industry must be wary of adversaries' attempts to exaggerate the impact of the opinion." Sayler & Thomas, *supra* note 22, at 207.

¹⁵¹ *Id.* at 200.

outside the section 510(k) realm. Twelve years after *Lohr*, it finally took the opportunity, and granted certiorari to *Medtronic v. Riegel*.¹⁵²

Part IV: *Medtronic v. Riegel*

The *Riegel* Court was poised to answer many questions that had cropped up during the decade that had passed since *Lohr*. Would the Court use the underlying message of *Bates* and *Sprietsma* to repudiate *Cipollone* and beef up protection for common-law tort actions? Or would they instead reaffirm *Cipollone* and expand the scope of preemption under the MDA? What weight, if any, would they give to FDA's change of heart? Most practically, what would be the status of the preemption defense for manufacturers whose devices had undergone the rigorous PMA process, instead of just section 510(k) review?

In May 1996, after having suffered a heart attack, Charles Riegel underwent an angioplasty – a procedure in which his surgeon attempted to dilate his right coronary artery. Riegel's artery was diffusely diseased and heavily calcified, but the surgeon successfully inserted a Medtronic-manufactured Evergreen Balloon catheter.¹⁵³ The catheter was a Class III device that had been FDA-approved in 1994 after undergoing the PMA process.¹⁵⁴ During inflation of the catheter, the device burst and Mr. Riegel developed a heart block. He was placed on life support and underwent emergency coronary bypass surgery.¹⁵⁵ Riegel and his wife brought a lawsuit in a New York federal district court, complaining that Medtronic's catheter was “designed, labeled and manufactured in a manner that violated New York common law” and that as a result of these defects, Charles Riegel had suffered permanent

¹⁵² 128 S. Ct. 1999 (2008).

¹⁵³ The labeling on the Evergreen Balloon Catheter stated that its use was contraindicated in patients with “diffuse or calcified stenoses.” The label also warned against inflating the catheter beyond its rated burst pressure of eight atmospheres, but the physician inflated it to a pressure of 10 atmospheres. *Id.* at 1005.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

injury.¹⁵⁶ The Riegels raised a number of common-law claims, and the district court found them all either to be preempted under the MDA or granted summary judgment to Medtronic.

The United States Court of Appeals for the Second Circuit affirmed the district court's holdings, finding that Medtronic was “clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved’ premarket approval application.”¹⁵⁷ The Second Circuit reasoned that the Riegels’ claims had to be preempted because if they prevailed on them, the verdicts would have “impose[d] state requirements that differed from, or added to’ the device-specific federal requirements.”¹⁵⁸ The Supreme Court granted certiorari.¹⁵⁹

Since *Cipollone*, *Lohr*, and other preemption cases in that line had already established that the word “requirements” in the MDA preemption clause could be read to include state common-law tort claims, the Court in *Riegel* proceeded directly to the two-part test for determining whether the claims at issue in this case were preempted. To streamline our discussion of the case, I will address the Court’s holdings under the following headings: (A) did the federal government establish requirements applicable to the Evergreen Balloon within the meaning of § 360k(a) of the MDA? (B) did the Riegels’ common-law claims rely upon any “requirements” under New York law that were specific enough to invoke § 360k(a) preemption?

¹⁵⁶ *Id.* at 1006.

¹⁵⁷ *Id.* (quoting *Medtronic, Inc. v. Riegel*, 451 F.3d 104, 118 (2d. Cir. 2006)).

¹⁵⁸ *Id.* (quoting *Medtronic, Inc. v. Riegel*, 451 F.3d 104, 121 (2d. Cir. 2006)).

¹⁵⁹ In the time between the initial filing of the complaint and the Supreme Court case, Charles Riegel died. The Court recognized his wife as petitioner and, for simplicity’s sake, it drew no formal distinction between Charles Riegel and his estate in the opinion. *Riegel*, 128 S. Ct. at 1006 n.3.

(A) *Did the federal government establish requirements applicable to the Evergreen Balloon within the meaning of § 360k(a) of the MDA?*

The majority opinion addressed this question first because the MDA expressly preempts only “state requirements ‘different from, or in addition to, any requirement applicable...to [a] device’ under federal law.”¹⁶⁰ The Court reiterated its findings in *Lohr*, which had been “substantially informed” by FDA regulations that extended the reach of the MDA preemption clause only to those situations where FDA has established specific requirements to govern the device in question.¹⁶¹ In *Lohr*, the federal “requirements” at issue were judged to be non-specific because the abbreviated section 510(k) process reflected “entirely generic concerns about device regulation generally.”¹⁶² In this case, however, the medical device had not merely undergone section 510(k) review; it had gone through the full PMA process.

Focusing on the rigorous, thorough, and time-consuming nature of PMA, the Court declared that in contrast to the section 510(k) process, “[PMA] imposes ‘requirements’ under the MDA as we interpreted it in *Lohr*.”¹⁶³ Unlike the generally applicable GMPs that govern Class I, Class II, and “grandfathered” Class III devices, PMA involves the imposition of requirements specific to the individual devices reviewed. Section 510(k) review focuses on equivalence, not safety, whereas PMA focuses on safety, not equivalence.¹⁶⁴ Because of the vast difference in the quantity and quality of review that FDA grants under the two pre-market review processes, the Court found that the PMA process met the “specificity” requirement laid out in *Lohr*. Thus, Class III devices that have undergone PMA are subject to federal “requirements” within the meaning of the MDA.

¹⁶⁰ *Id.* at 1006 (citing 21 U.S.C. § 360k(a)(1)).

¹⁶¹ *Id.* (relying on 21 C.F.R. § 808.1(d)).

¹⁶² *Id.* (quoting *Lohr*, 518 US at 501).

¹⁶³ *Id.* at 1007.

¹⁶⁴ *Id.*

(B) Did the Riegels' common-law claims rely upon any "requirements" under New York law that are specific enough to invoke § 360k(a) preemption?

Whereas the first prong of the test involved the Court determining the specificity of the federal requirements to which the device was subject, the second prong required an examination of the specificity of the state requirements at issue. The key question was whether the Riegels' common-law claims relied upon "any requirement" of New York law applicable to the Evergreen Balloon catheter that was "different from, or in addition to" federal requirements and that 'relate[d] to the safety or effectiveness of the device.'"¹⁶⁵ In short, were New York's tort-based common-law duties also "requirements" within the meaning of the MDA?

Again, the Court cited its reasoning in cases like *Cipollone* and *Bates*, which had resulted in finding some common-law actions preempted. According to Justice Scalia's majority opinion, "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties." A liability award in a tort case "can be, indeed is designed to be, a potent method of governing conduct and controlling policy."¹⁶⁶ The Court found that if, under state tort law, the catheter would have needed to be safer and thus potentially less effective than the model that FDA approved, such a common-law duty would "disrupt[] the federal scheme no less than state regulatory laws to the same effect."¹⁶⁷ Along these lines, the Court reasoned that state common-law duties that flew in the face of federal requirements as specific as those entailed in the PMA process were likely to fall within the scope of preemption.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 1008 (citing *Cipollone*, 505 U.S. at 521).

¹⁶⁷ The Court indicated that such common-law duties might warrant even *less* protection than preemption from regulations promulgated by state agencies and legislatures (which are clearly preempted by § 360k), because of the lay and unpredictable nature of jury verdicts. *Id.*

The Court did take note of FDA's shift from an anti-preemption stance in the immediate post-*Lohr* era to a pro-preemption stance in more recent years. However, the Court found it unnecessary to place any official weight on the agency's opinion because the statute was determined to be clear on its face.¹⁶⁸ In terms of whether FDA's turnabout *would* have had any impact on the Court's interpretation had they needed agency advice, the Court noted that the degree of deference they would have accorded "might be reduced by the fact that the agency's earlier position was different."¹⁶⁹

The Riegels argued that the state common-law duties on which their claims relied were not specific enough to trigger the preemption clause of the MDA. After all, general tort law duties are not promulgated "with respect to devices." The Court summarily dismissed this argument though, finding that there was nothing in the statute to indicate that the state requirement at issue had to apply *only* to the medical device in question or only to medical devices as a category.¹⁷⁰ The Court thus found the Riegels' claims to be preempted under the MDA.

In conclusion, the Court explicitly reiterated one remaining avenue for relief, which it had also noted in *Lohr* – nothing in the MDA would prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations. Basically, as long as the state duties under which a tort claim was brought ran parallel to the federal regulations, rather than adding to them, such a claim would survive preemption. Unfortunately, the Riegels waived the argument that their complaint alleged parallel claims by not raising it in

¹⁶⁸ "We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue." *Id.* at 1009.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 1010.

the lower courts or in their petition for certiorari. As a result, the Court was unable to address whether their claims could have survived in this category.¹⁷¹

Justice Stevens wrote a concurring opinion in which he emphasized his interpretation of the underlying purpose of the MDA. He believed it was enacted to provide additional protection to consumers, and not to withdraw existing protections. At the same time, he concurred that the Riegels' claims were preempted. Much as he thought that Congress was originally concerned with conflicting state statutes and regulations when it drafted the MDA preemption clause, the fact remained that the language could be plausibly read to include other "requirements" such as those imposed by state common-law duties. In this case, he felt that the Riegels' claims were premised on New York common-law duties that triggered the "different from" language of the MDA and that related to the safety and effectiveness of the Evergreen Catheter. In light of the specific federal requirements with which these common-law duties would conflict, such claims were worthy of preemption within the language of the clause.¹⁷²

Ginsburg's dissent took issue with the Court's construal of Congressional intent in enacting the MDA. Even though she had admitted in *Lohr* that the language of the preemption clause could be read to encompass some state common-law duties, she cautioned against the "sweeping preemption of mine-run claims for relief under state tort law" that the *Riegel* majority now endorsed.¹⁷³ She posited that the narrow forms of relief that would still be available in the post-*Riegel* era would not help consumers injured by devices that received FDA approval, but that later proved to be unsafe. The MDA's failure to create any federal compensatory remedy for this category of sufferers suggested to her that Congress could not have intended to preempt state common-law suits so broadly, especially if they were

¹⁷¹ *Id.* at 1011.

¹⁷² *Id.* at 1012-13.

¹⁷³ *Id.* at 1014 (Ginsburg, J., dissenting).

grounded on allegations independent of FDA requirements.¹⁷⁴ Ginsburg found it “‘difficult to believe that Congress would, without comment, remove all means of judicial recourse’ for large numbers of consumers injured by defective medical devices.”¹⁷⁵ In her consumer-protective analysis of Congressional intent, she considered the regulatory regime that predated the enactment of the MDA. Before 1976, many of the states had installed their own medical device control regimes, and she saw this as the motivating factor for Congress’ decision to include § 360k(a) in the law, rather than any specific plan to suppress tort suits.¹⁷⁶

Ginsburg concluded by pointing out that even if the Court had not chosen to read § 360k(a) as an automatic bar to state common-law claims, it would not necessarily have rendered moot the fact that the Evergreen Balloon catheter had undergone PMA review. Express preemption under the statute was not the only defense a device manufacturer could assert. Instead, Medtronic could have asserted conflict preemption; if it could identify an actual conflict between the plaintiffs’ theory of the case and the FDA’s approval of the device following PMA review, the tort claim may have still been preempted. Because Medtronic did not advance this argument, however, the Court did not address this possibility.¹⁷⁷ Another way in which the PMA process could be relevant is if the manufacturer used it to present a regulatory compliance defense. Essentially, Medtronic could have presented the fact that FDA approved its device as *prima facie* evidence that it used due care in product design and labeling. Ginsburg acknowledged that the regulatory compliance defense was not dispositive in most states; it would just be one of many factors for the jury to consider. Nonetheless, these were valid examples of instances in which the preemption defense for manufacturers could have survived even if the Court had adopted a more narrow reading of the scope of express preemption under § 360k(a). Ginsburg’s dissent indicated clear disapproval of the

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* (citing *Silkwood*, 464 U.S. at 251).

¹⁷⁶ *Id.* at 1018.

¹⁷⁷ *Id.* at 1019-20.

Court's rationale and its holding, stating that "[t]he constriction of state authority ordered today was not mandated by Congress and is at odds with the MDA's central purpose: to protect consumer safety."¹⁷⁸

Partially in response to Ginsburg's scathing dissent, Scalia's opinion expressly stated that it was not the Court's job to "speculate upon congressional motives."¹⁷⁹ Even if such an inquiry into Congressional intent were necessary though, the Court said that the only reliable indicator of Congressional intent available to them was the text of the statute itself. As the majority saw it, the MDA's text implied that any "solicitude [Congress may have had] for those injured by FDA-approved devices...was overcome in Congress's estimation by solicitude for those who would suffer without medical devices if juries were allowed to apply the tort law of 50 States to all innovations."¹⁸⁰

In sum, *Riegel* provides immunity to manufacturers whose products have undergone PMA review. If FDA has approved a device's design and labeling in the PMA process, an injured plaintiff can no longer bring a tort suit against the manufacturer in state court alleging design or labeling defect. *Riegel* thus explicitly expands the scope of preemption under the MDA to cut off an avenue of relief for a subset of injured victims. After this case, the only damages remedies available in state courts are for claims that allege that the manufacturer violated FDA regulations in the design and marketing of the device.

Part V: Post-*Riegel* Wranglings

Before *Riegel*, most jurisdictions that had confronted the issue had already held that § 360k(a) of the MDA preempted conflicting state common-law claims arising from the design,

¹⁷⁸ *Id.* at 1020.

¹⁷⁹ *Id.* at 1009.

¹⁸⁰ *Id.*

manufacture, and labeling of a medical device that had undergone PMA.¹⁸¹ *Riegel* thus provided resounding support for their holdings. Even though the case did not explicitly address what would have happened if the medical device had entered the market after the IDE process, the *Riegel* rationale supports a prediction that state tort claims in this context will likely be preempted as well.¹⁸² The IDE process, much like PMA, is a very rigorous and fact-intensive investigation on FDA's part, and this would most likely result in a court finding such a device to be subject to adequately specific federal "requirements" within the meaning of the MDA.

The holding in *Riegel* does not suggest, as some commentators predicted prior to the case, that the Court is taking a particularly "narrow view of claims that common-law duties are preempted."¹⁸³ In fact, while *Lohr* merely suggested that some common-law duties might be preempted, *Riegel* actually defines a category of claims in which plaintiffs will be denied judicial relief.

The *Riegel* decision is so new that it is too early to tell the full extent of the case's impact. Exactly how many plaintiffs will have their cases dismissed? How many device manufacturers will prevail on summary judgment in the immediate aftermath of this holding? The numbers suggest that while the rationale and holding in *Riegel* are pro-defendant, the statistical impact the case will make is slight. Recall that section 510(k) remains the dominant mode of market entry for Class III devices, and under *Lohr*, plaintiffs can still bring state common-law based tort claims in these cases.¹⁸⁴ As a result, *Riegel* may still allow the

¹⁸¹ Joyce B. Margarce & Michelle R. Scheiffele, *Is the Preemption Defense for PMA-Approved Medical Devices in Jeopardy?* 75 DEF. COUNS. J. 12, 12 n.1 (citing cases in the 2nd, 3rd, 5th, 6th, 7th, and 8th Circuits, Texas, Rhode Island, and Pennsylvania that had already issued rulings consistent with *Riegel*).

¹⁸² Carrier, *supra* note 33, at 560.

¹⁸³ HUTT, MERRILL & GROSSMAN, *supra* note 5, at 1490.

¹⁸⁴ 98.99% of new devices cleared for marketing by FDA in 2005 were cleared under section 510(k) rather than PMA. *Id.* at 992. See also Brief for Appellee-Respondent at 49,

vast majority of claims involving Class III devices to proceed. The one arena in which the holding represents a real judicial shutout is in the category of devices that are approved by FDA after PMA. While these devices are a statistical minority, they are still prevalent and some do cause catastrophic injury.¹⁸⁵ Also, even though the number of PMA devices approved per year is comparatively small, FDA handles hundreds of “supplements” to existing PMAs that reflect design or manufacture changes to devices already on the market. Numerous lower court decisions say such supplements have the same legal status as the original approvals, even though they often receive less thorough review and are approved in a matter of weeks.¹⁸⁶ The *Riegel* case may thus impact cases involving devices that were altered after mere supplementary review as well. Even though *Riegel* leaves avenues of relief open for many plaintiffs injured by Class III devices, how do we feel about the fact that patients like Charles Riegel will have no legal recourse? Does *Riegel* strike an optimal balance between federal goals and states’ rights, or between medical innovation and consumer safety?

In this author’s opinion, preemption in the post-*Riegel* world is probably not the regime that Congress intended when it enacted the MDA.¹⁸⁷ The Court seems to have taken a wrong turn as far back as *Cipollone*, or at least as far back as *Lohr*, when it imported the logic of *Cipollone* to the context of the MDA in finding that “requirements” could encompass

Medtronic, Inc. v. Riegel, 128 S. Ct. 999 (2008) (No. 06-179) (asserting that 99% of of Class III devices enter the market via the 510(k) process).

¹⁸⁵ “Daily front-page stories about harmful medical devices on the market such as defective Guidant defibrillators, Medtronic and Baxter infusion pumps, and Johnson & Johnson Boston Scientific heart stents, raise serious questions about the ability of the FDA approval process to provide adequate assurance of safety by itself.” Vladeck, *supra* note 37, at 101-02. See also Barnaby J. Feder, *Medical Device Ruling Redraws Lines on Lawsuits*, N.Y. TIMES, Feb. 22, 2008, at C2, available at 2008 WLNR 3482978 (listing examples of cases pending in the post-*Riegel* world that are in danger of dismissal).

¹⁸⁶ Feder, *supra* note 185, at C2.

¹⁸⁷ “There is not a hint in the legislative history of the MDA that Congress intended that the amendments would restrict the right of injured persons to bring state law damage actions for compensation.” Vladeck, *supra* note 37, at 103 (citing *Lohr*, 518 U.S. at 490-91 & nn.12 & 13).

state common-law duties. In light of the fact that the Court began its express preemption analyses with broad statements about the importance of state sovereignty and the presumption that Congress does not “cavalierly pre-empt state-law causes of action,”¹⁸⁸ it seems very odd indeed that it went on to expand the scope of preemption under the MDA in the absence of clear Congressional guidance. The Court itself admitted that there was no evidence that Congress contemplated extinguishing state common-law tort claims with the insertion of § 360k(a).¹⁸⁹ Especially in light of the litigation-heavy, consumer safety-focused period of time in which the MDA was enacted, it seems exceedingly strange that Congress would work such a change on future injured plaintiffs without using language that was unmistakably clearer than present-day § 360k(a). Aside from the lack of concrete evidence of intent in the Congressional record, the fact remains that FDA regulations (poorly worded though they may be) showed that the agency did not believe state common-law tort claims fell within the preemptive reach of § 360k(a). One would think that the combination of non-intent and contrary intent from both Congress and the agency vested with the power to enforce the relevant statute would be enough to persuade the Court that common-law claims fell outside the reach of this preemption clause.¹⁹⁰

¹⁸⁸ Lohr, 518 U.S. at 485.

¹⁸⁹ “There is, to the best of our knowledge, nothing in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation.” Lohr, 518 U.S. at 491.

¹⁹⁰ Perhaps though, even those who would argue that Congress did not intend the MDA preemption clause to subsume the important functions of state tort law should take solace in the fact that *Lohr*: (a) restricted *Cipollone* to its facts, and (b) conducted an analysis of requirement specificity that resulted in *saving* the Lohrs’ claims from preemption. In that sense, even though *Lohr* might be criticized for opening the door to federal preemption of state law claims in the absence of clear Congressional intent, it may simultaneously be commended for not running amok with *Cipollone*’s language and finding *all* common-law tort claims preempted.

Another indication of a judicial misstep was the *Lohr* Court's newly minted two-part test to determine *which* common-law actions would fall within the scope of the MDA preemption clause. In light of the "assumption that the historic police powers of the States were not to be superseded by the [MDA] unless that was the clear and manifest purpose of Congress,"¹⁹¹ it seems surprising that the Court would need to develop its own test to distinguish those "requirements" worthy of preemption from those that were not. If Congress did not make such a distinction clear enough in the statute, the Court was disingenuous in trying to invent its own system to add clarity.

Even though this author believes *Lohr* was a mistake to begin with, there are problems with MDA preemption doctrine even if we assume that that case was rightly decided. The *Riegel* decision conflicts with the language in *Lohr* in crucial ways that suggest that the Court should be aware of its own inconsistencies. For example, the Court in *Lohr* stated that "'the purpose of Congress is the ultimate touchstone' in every pre-emption case."¹⁹² Scalia's majority opinion in *Riegel*, in contrast, stated that it was "not [the Court's] job to speculate upon congressional motives" in determining the scope of the MDA preemption clause.¹⁹³ Another example of contradictory reasoning was the fact that the *Lohr* and *Riegel* Courts disagreed over the clarity of the MDA's text. The *Lohr* Court admitted to finding ambiguity in the statutory wording.¹⁹⁴ It needed to import legislative history, reasoning from other cases like *Cipollone*, and relevant FDA regulations to make sense of the language.¹⁹⁵ The *Riegel* Court, however, stated that the MDA itself was clear and

¹⁹¹ *Lohr*, 518 U.S. at 485 (citations omitted).

¹⁹² *Id.* at 494 (citing *Cipollone*, 505 US at 516) (internal quotation marks and citations omitted).

¹⁹³ *Riegel*, 128 S. Ct. at 1009.

¹⁹⁴ "First, the MDA's pre-emption provision is highly ambiguous." *Lohr*, 518 U.S. at 505.

¹⁹⁵ "Second, this Court has previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect... To draw a similar inference here makes sense, and not

unambiguous enough to be read without reliance on either legislative history or FDA guidance.¹⁹⁶ A final example of inconsistency would be the Court's shifting perspective on what Congress' use of an admittedly "broad" term in the MDA – "requirements" – should mean. A plurality of the *Lohr* Court counseled caution against a sweeping interpretation, saying that "if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it."¹⁹⁷ The *Riegel* majority, however, interpreted Congress' use of broad language far more openly, declaring that "in the context of this legislation [,] excluding common-law duties from the scope of pre-emption would make little sense."¹⁹⁸ Essentially, the Court exhibited crucial shifts in reasoning between *Lohr* and *Riegel*, which should make us hesitant to embrace the final output of these decisions as perfectly cogent and doctrinally sound.

Next, even if we embraced the holding of *Lohr*, the Court's application of the *Lohr* two-part test to the facts of *Riegel* was suspect. Recall that the test required the Court to consider the specificity of both the federal requirements to which the medical device was subject, *and* the state requirements that the tort suit would allegedly impose on the manufacturer if such a suit were allowed to proceed. In *Lohr*, the section 510(k) process was found to be inadequately rigorous to constitute a specific set of federal requirements. In *Riegel*, PMA review was deemed to be far more specific. While such a distinction seemed

simply because of the statutory ambiguity. The Food and Drug Administration (FDA) is fully responsible for administering the MDA...That responsibility means informed agency involvement and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives." *Id.* at 506.

¹⁹⁶ "We have found it unnecessary to rely upon that agency view because we think the statute itself speaks clearly to the point at issue. If, however, we had found the statute ambiguous and had accorded the agency's current position deference, the dissent is correct...that -- inasmuch as mere *Skidmore* deference would seemingly be at issue -- the degree of deference might be reduced by the fact that the agency's earlier position was different." *Riegel*, 128 S. Ct. at 1009.

¹⁹⁷ *Lohr*, 518 U.S. at 487.

¹⁹⁸ *Riegel*, 128 S. Ct. at 1008.

plausible and sound, the *Riegel* Court's analysis of the second prong of the test was not. In *Lohr*, the Court found that since the general state common-law duties on which the Lohrs' complaint rested were not generated "with respect to" medical devices, they were not specific enough to impose "requirements" on the device within the meaning of the MDA.¹⁹⁹ Yet in *Riegel*, the Court switched without explanation to an effects-based test of whether the state requirements were specific enough. The Court found that since the New York common-law duties on which the Riegels' complaint rested would have the *effect* of imposing different substantive requirements on a medical device, it did not matter whether or not they were developed "with respect to" devices specifically or not – they would be preempted.²⁰⁰ This tortured application of the test gives us reason to question whether specificity of the state requirements was ever important at all in evaluating of the scope of MDA preemption. In the post-*Riegel* world, it seems as though the test may have only one prong. Provided that the federal requirements are specific enough, state tort suits will likely be preempted, regardless of how general the allegedly conflicting state common-law duties are.

Aside from the inconsistencies in the Court's treatment of preemption under the MDA, we cannot ignore the strange about-face performed by FDA as well. In the pre-*Lohr*

¹⁹⁹ "Similarly, the general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Lohr*, 518 U.S. 501-02.

²⁰⁰ "The Riegels' suit depends upon New York's 'continu[ing] in effect' general tort duties 'with respect to' Medtronic's catheter. Nothing in the statutory text suggests that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general." *Riegel*, 128 S. Ct. at 1010.

era and in the immediate aftermath of the case, FDA supported a much narrower reading of § 360k(a) than the one espoused by the Supreme Court. Remarkably, by the time the Supreme Court decided *Riegel*, the agency had changed its outlook and was suddenly in favor of a very broad reading of the claims the MDA should preempt. What should we make of this change? While the *Lohr* Court's decision was substantially informed by the FDA regulations at the time, the *Riegel* Court claimed not to accord the agency's unofficial position any deference. One might wonder whether this was even true, considering the fact that the Court's own viewpoint on the scope of MDA preemption seemed to expand along with FDA's from *Lohr* to *Riegel*. Regardless of how one feels about the agency's change, it does suggest that something may be amiss, and the chances of the MDA's underlying purpose having been misconstrued or being misconstrued in future are great.

Inconsistencies in the Court and the agency positions aside, one may ask whether the post-*Riegel* landscape is a good place to be from a policy perspective. A pro-defendant argument would be that a generous reading of § 360k(a) is necessary to protect manufacturers from inconsistent treatment and conflicting requirements in state courts, thus promoting a coherent federal regulatory scheme that will foster medical innovation. Under this viewpoint, preemption is good and will result in wide benefits being realized by consumers. Preemption is not necessarily the enemy of consumer safety under the modern regime because devices that are not heavily regulated by FDA (such as Class I, Class II, and section 510(k)-reviewed Class III devices) are still open battlegrounds for state lawsuits. Also not preempted are tort suits that enforce state common-law duties that merely replicate the federal requirements. In this way, provided that we trust FDA to regulate medical devices, the current view of the preemption clause does not endanger anyone. Manufacturers like Medtronic argue that "the preemptive effect of the PMA process *enhances* the safety of medical devices" by incentivizing manufacturers to subject their products to the rigorous PMA process rather than

the substantially more relaxed section 510(k) notification process.²⁰¹ The argument is that if, by undergoing PMA review, manufacturers will essentially be shielded from the prospect of state product liability lawsuits, they will be more likely to submit to thorough review than merely taking the section 510(k) shortcut. The resulting higher number of devices undergoing PMA review will mean enhanced safety of devices on the marketplace.

From a pro-plaintiff standpoint, it seems as though the current broad reading of § 360k(a) deprives parties injured by unsafe medical devices of much-needed legal recourse. Even though PMA review is supposed to be thorough and rigorous, the fact remains that it is heavily dependent on data submitted by the device manufacturers themselves, and these may exclude unfavorable results. On top of that, FDA is chronically underfunded,²⁰² requiring it to rely on user fees paid by manufacturers to fund the market review process – a practice which could influence agency approval.²⁰³ Even if the federal government has consumers' best interests at heart, it simply may not have the resources to safeguard the public from dangerous medical devices all by itself.²⁰⁴ Another concern is that the post-*Riegel* landscape will not even provide injured plaintiffs with the few avenues for legal relief that supposedly do remain open. For example, even though plaintiffs are still allowed to bring state tort suits alleging that a device manufacturer violated federal requirements, *Riegel* may result in judges

²⁰¹ Brief for Appellee-Respondent at 49, *Medtronic, Inc. v. Riegel*, 128 S. Ct. 999 (2008) (No. 06-179) (emphasis added).

²⁰² Elizabeth Newell, *FDA still underfunded, say lawmakers*, GOVERNMENT EXECUTIVE, Feb. 8, 2008, available at <http://www.govexec.com/dailyfed/0208/020808e2.htm>.

²⁰³ “A survey conducted by nonprofit organizations found that 60 percent of FDA scientists knew of cases in which commercial interests had influenced FDA approval, and that one-third of outside scientists enlisted by the FDA to aid in product approval had a financial interest of more than \$50,000 in the manufacturer of that product.” Suzanne Cook, Michael Litvin & Cecelia Sander Cannon, *Supreme Court Preview: Riegel v. Medtronic*, 55-FEB. FED. LAW. 61, 62 (2008).

²⁰⁴ As mentioned earlier, once a device has been PMA-approved, a manufacturer can still make significant design and manufacture changes by filing an abbreviated supplementary application. There are currently lawsuits pending that relate to the Sprint Fidelis pacemaker lead – a device that underwent a substantial structural change, but that was approved by FDA in fewer than 30 days via the PMA supplementary application. Feder, *supra* note 185, at C2.

dismissing these cases before plaintiffs' lawyers can gain enough evidence via discovery to prove such violations.²⁰⁵ The resulting effect may be sweeping preemption of substantially *all* lawsuits involving Class III medical devices. There are reasons to believe that the "tort and regulatory systems [can] operate in tandem and place separate, albeit reinforcing, disciplines on the market."²⁰⁶ Tort litigation can operate to fill gaps in the regulatory scheme that agencies cannot fill by themselves.²⁰⁷ For these reasons, perhaps our current understanding of preemption under the MDA has tipped the balance too much towards federal control and manufacturer immunity, and too far away from the underlying goal of protecting the public from dangerous and defective medical devices.

Conclusion

It has been a long time since we saw them, but let us return to our Jane and John Doe, waking up in the world after *Riegel*. Jane's company is thrilled and tells her to start drafting summary judgment motions by the dozen. So many lawsuits have simply evaporated overnight because, after all, Acme's joints were PMA-approved. Jane goes out to celebrate her good fortune. John phones a lawyer to inquire about his chances of prevailing in a product liability suit against Acme. The plaintiffs' lawyer on the other end of the line has been on the phone all morning, breaking the bad news gently to dozens of unsuspecting clients whose own lawsuits against medical device manufacturers were pending. John finds it difficult to believe that he can't hold Acme accountable for his current medical condition. How is it that they can just hide behind a review process that clearly didn't even work?

There is a glimmer of hope – perhaps he can sue Acme for improperly manufacturing the joint – building it to specifications different from the ones that FDA authorized. But the

²⁰⁵ *Id.*

²⁰⁶ Vladeck, *supra* note 37, at 132.

²⁰⁷ *Id.*

lawyer tells John that even this is a long shot. They would need to get their hands on lots of evidence to even make the case seem plausible...but they can try. John, exhausted and embittered, decides that the slim chance is not worth the expense and hassle of litigation. He hangs up the phone and shakes his head in disbelief.

The post-*Riegel* world is still brand new, and it is very possible that major developments are just around the corner. There is, in fact, hope that the author of it all – Congress – will step in again to clear up the mess that courts and FDA have made of § 360k(a). As Senator Ted Kennedy said when he proposed the MDA, the law was “written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions.”²⁰⁸ Right after the Court announced its decision in *Riegel*, Senator Kennedy and Representative Henry Waxman (who was also instrumental in the passage of the MDA in 1976) joined together to say that the ruling was contrary to Congress’s intent and that they would introduce legislation to overturn it.²⁰⁹ The real challenge Congress will face is in drafting language that will leave no room for doubt this time. Thankfully, there is a plethora of court cases to guide legislators on how *not* to be misinterpreted again.

Jane Doe and Acme may be safe for the moment, and John Doe may suffer in relative silence. But there is reason to believe that *Riegel* is not the last we will hear of preemption under the MDA, and the tables may turn again sooner than we think.

²⁰⁸ 121 CONG. REC. 10688 (daily ed. Apr. 17, 1975) (statement of Sen. Kennedy).

²⁰⁹ Feder, *supra* note 185, at C2.